ONLY CONGRESS THROUGH NEW LEGISLATION CAN CHANGE THE LAW THAT THE FDA HAS NO JURISDICTION OVER CIGARETTES MARKETED WITHOUT THERAPEUTIC CLAIMS

THE FOOD, DRUG AND COSMETIC ACT DOES NOT GRANT THE FDA JURISDICTION OVER CIGARETTES MARKETED WITHOUT THERAPEUTIC CLAIMS:

- The sole source of the FDA's legal authority to regulate products is the Food, Drug, and Cosmetic Act (the "Act"). Under the Act, the FDA can regulate a product as a "drug" only when that product is "intended for use in the . . . treatment or prevention of disease in man . . . [or] . . . intended to affect the structure or function of the body of man." 21 U.S.C. §§ 321(g)(1)(B), 321(g)(1)(C).

- Whether a product is intended for use as a drug "is determined from objective evidence such as the product's current and past containers, instructions, and advertisements." See, e.g., Estee Lauder, Inc. v. Food and Drug Administration, 727 F. Supp. 1, 2 (D.D.C. 1989).

- In the specific context of cigarettes, both the FDA and the courts have therefore recognized that any FDA jurisdiction lies "in the manufacturers' representations as revelatory of their intent." Action on Smoking and Health v. Harris, 655 F.2d 236, 237 (D.C. Cir. 1980). Cigarettes sold only for smoking pleasure, without any claimed therapeutic or bodily benefit, are thus not subject to FDA jurisdiction.

PAST PRECEDENTS SUPPORT FDA'S LACK OF JURISDICTION:

- The FDA, the courts and Congress share a long and consistent understanding that FDA has no jurisdiction over cigarettes marketed without therapeutic claims.

- FDA: For more than 80 years, FDA (and its predecessor agencies) have consistently taken the position, internally, before Congress and before the courts, that the Agency does not have jurisdiction to regulate cigarettes unless the manufacturer makes an express claim of some therapeutic benefit.

- The Congress: Congress has accepted the FDA's long-standing interpretation of the Act as denying it

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jurisdiction over any cigarettes other than those expressly marketed as having a therapeutic function. Despite at least 69 amendments to the Act, Congress has never overruled or nullified FDA's long-standing interpretation that it lacks jurisdiction over cigarettes.

-- Moreover, the FDA has told Congress repeatedly, and Congress has understood, accepted and acquiesced in the position that legislation excluding tobacco products from FDA's jurisdiction is unnecessary because FDA has no authority absent therapeutic claims. As the Supreme Court has stated: "[O]nce an agency's statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned." United States v. Rutherford, 442 U.S. 544, 554 n.10 (1979) (emphasis added).

-- Last, but by no means least, Congress has on numerous occasions failed to enact legislation to give the FDA jurisdiction over tobacco products. Rather, as noted below, Congress has preempted the field of cigarette regulation and labeling to itself and as delegated to other agencies, excluding FDA.

- The courts: The courts have upheld the FDA's position that it does not have jurisdiction to regulate as "drugs" cigarettes marketed without therapeutic claims and have noted specifically that Congress has long acquiesced in that position. See, e.g., Harris, 655 F.2d at 241-42.

KESSLER'S PROPOSAL REPRESENTS A DRAMATIC DEPARTURE FROM SUCH PRECEDENTS:

- Commissioner Kessler's proposal to regulate tobacco products as drugs therefore represents a radical change in direction and departure from long-standing past precedent and practice. Such a proposal raises, by the Commissioner's own acknowledgment, "societal issues of great consequence and magnitude." (See 2/25/94 letter from Dr. Kessler to Coalition on Smoking OR Health ("COSH").)

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ANY SUCH SHIFT CAN ONLY BE ACCOMPLISHED BY THE ENACTMENT OF NEW LEGISLATION:

- A public policy decision of this magnitude should be made only by elected officials, not nonelected bureaucrats. The case law is clear that congressional acquiescence in an agency's interpretation of a statute -- as in the case of the FDA's historic position on its authority to regulate cigarettes -- constitutes a clear presumption of legislative intent and prevents the FDA from adopting a new standard of jurisdiction without enactment of new legislation by Congress. See National Labor Relations Board v. Bell Aerospace Co., 416 U.S. 267 (1974).

- Commissioner Kessler has repeatedly solicited "clear direction" from Congress and has pledged to "work with Congress to resolve" this issue. (See, e.g., 2/25/94 COSH letter.) The FDA should heed its own words and let Congress provide the proper policy direction.

CONGRESS HAS RESERVED TO ITSELF THE MAJOR POLICY DECISIONS ABOUT CIGARETTES:

- Regulation of cigarettes as "drugs" by the FDA would not only be beyond the Agency's statutory authority under the Act, but also would fly in the face of the carefully crafted and comprehensive scheme that Congress has developed to regulate tobacco products.

- Federal policy on the regulation of cigarettes has been clear for 30 years. The purpose of the Federal Cigarette Labeling and Advertising Act ("FCLAA") is "to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." 15 U.S.C. § 1331. This comprehensive scheme has been reconsidered many times, but Congress has consistantly determined that cigarettes should be available to the public under a framework that excludes any role for the FDA in regulating the tobacco industry.

- Congress has unambiguously expressed its intention to maintain primary control over the health aspects of tobacco products. Pursuant to this control, Congress has subjected cigarettes and other tobacco products

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to an extensive series of statutory requirements, and Congress has made its position clear on the appropriate level of regulation for tobacco products.

-- One congressional report summed up precedent in this area as supporting "the clear mandate of Congress that the basic regulation of tobacco and tobacco products is governed by legislation dealing with the subject, the Cigarette Labeling and Advertising Act . . . , and that any further legislation in this sensitive and complex area must be reserved for specific Congressional action." S. Rep. No. 251, 94th Cong., 2d Sess. 43, reprinted in, 1976 U.S. Code Cong. & Admin. News, 993, 1012.

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